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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,280	08/27/2003	Kenneth W. Wood	UCSD-07982	6632

23535 7590 04/11/2007  
MEDLEN & CARROLL, LLP  
101 HOWARD STREET  
SUITE 350  
SAN FRANCISCO, CA 94105

EXAMINER
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HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/650,280

Applicant(s)

WOOD ET AL.

Examiner

Anne L. Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-22, 24, 25, 27-29, 35, 43-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-54 is/are allowed.
- 6) ☒ Claim(s) 17-20, 24, 25, 27-29, 35 and 43 is/are rejected.
- 7) ☒ Claim(s) 21, 22 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____                                                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____                                                              | 6) <input type="checkbox"/> Other: ____                                     |

### **DETAILED ACTION**

1. The amendment filed 12/12/2006 is acknowledged. Claims 23, 26, 30-34 were canceled.

Claims 43-54 were added.

Claims 17-22, 24, 25, 27, 29, 35 and 43-54 are pending and examined on the merits.

#### ***Claim Rejections Withdrawn:***

#### ***Claim Rejections - 35 USC § 112***

2. The rejection of claims 17-35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

3. The rejection of claims 26-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment canceling claim 26.

3. The rejection of claims 17-19, 23 and 24 under 35 U.S.C. 102(b) as being anticipated by Lombillo (Lombillo, V. et al., The Journal of Cell Biology, 128(1&2): 107-115, 1995; cited in the IDS) is withdrawn in view of the amendment adding the active step of "providing a substantially purified biologically active CENP-E".

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4. The rejection of claims 17-19, 24 and 25 under 35 U.S.C. 102(b) as being anticipated by Thrower (Thrower, D.A., et al, The EMBO Journal, 14(5): 918-926, 1995; cited in the IDS) is withdrawn in view of the amendment adding the active step of "providing a substantially purified biologically active CENP-E".

5. The rejection of claims 17, and 20-22 under 35 U.S.C. 103(a) as being unpatentable over Lombillo (supra) in view of Duesbery (Duesbery, N.S. et al. Proc. Natl. Acad. Sci., USA, 94: 9165-9170, 1997, August; cited in the IDS) is withdrawn in view of the amendment adding the active step of "providing a substantially purified biologically active CENP-E".

6. The rejection of claims 17 and 35 under 35 U.S.C. 103(a) as being obvious over Lombillo (supra) or Thrower (supra) in view of Jubin (US 5,759,795; issued 6/2/1998; effective filing date 3/8/1996) is withdrawn in view of the amendment adding the active step of "providing a substantially purified biologically active CENP-E".

***Claim Rejections Maintained:***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 17-20, 24, 25, 27-29, 35, and 43 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of identifying a candidate agent that modulates CENP-E activity, where CENP-E is characterized by SEQ ID NO, does not reasonably provide enablement for methods of identifying candidate agents that modulate any and all proteins characterized by CENP-E that “corresponds to the amino acid sequence of 1-324 of SEQ ID NO: 1”, or that has 70% sequence identity with SEQ ID NO: 1 or amino acids 1-324 of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The amendments to the claims do not overcome the rejection of record. Applicants' arguments are not found persuasive, because they do not address the unpredictability of the relationship between amino acid sequence and protein function. As indicated in the previous Office action, the study of the relationship between the primary amino acid sequence and protein function is highly unpredictable. Bowie et al (Science, 247: 1306-1310, 1990) teaches that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Burgess et al (J. Cell Biology, 111 : 2129-2138, 1990) teaches that replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Lazar et al (Molecular and Cellular Biology, 8: 1247-1252, 1988) teaches that replacement of aspartic acid at position 47 with alanine or asparagines does not affect biological activity while replacement with serine or glutamic acid sharply reduces the

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biological activity of the protein. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. Because of the unpredictability of the protein arts, the skilled artisan cannot make and use the broad genus of methods that involve the use of "CENP-E" or "human CENP-E" or "Xenopus CENP-E" recited in the claims because such a genus encompasses proteins having an unlimited and thereby infinite plurality of amino acid substitutions, deletions, additions, or combinations thereof, as compared with the working embodiments. Therefore, the rejections are maintained for the reasons of record.

### ***Conclusion***

Claims 17-20, 24, 25, 27-29, 35, and 43 are rejected. Claims 21, 22 and 44 are objected to for depending from a rejected claim. Claims 45-54 are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
April 2, 2007



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER